



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Aladar Szalay et al.  
Serial No. : 10/849,664  
Filed : May 19, 2004

Art Unit : 1633  
Examiner : Robert M. Kelly  
Cust. No. : 20985  
Conf. No. : 7765

Title : LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS  
AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR  
INFLAMED TISSUE

**Mail Stop: Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (2 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item AC (EP1020197) is in the German language and an English language equivalent (Item AB) is listed. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EV 740126034 US  
Date of Deposit December 13, 2006  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

12/18/2006 EAREGAY1 00000024 10849664

01 FC:1806

180.00 0P

Provided herewith is a copy of a European Examination Report, issued October 2, 2006, in connection with European Patent Application No. 02012552.2 (Attorney Docket No. 17248-004EP1/ 4804EP). In the European Examination Report, Examiner cites seven documents: D3 (WO0125399), D4 (EP1020197), D5 (Parrish *et al.*, "Targeting widespread sites of damage in dystrophic muscle: engrafted macrophages as potential shuttles" *Gene Therapy*, 3:13-20 (1996)), D6 (Deng *et al.* "Engineering Ex Vivo-Expanded Marrow Stromal Cells to Secrete Calcitonin Gene-Related Peptide Using Adenoviral Vector" *Stem Cells* 22:1279-1291 (2004)), D7 (Van Damme *et al.* "Bone Marrow Stromal Cells as Targets for Gene Therapy" *Curr. Gene Ther.*, 2:195-209 (2002)), D8 (Cioffi *et al.* "A novel endothelial cell-based gene therapy platform for the in vivo delivery of apolipoprotein E" *Gene Therapy* 6:1153-1159 (1999)), D9 (Torrente *et al.* "Intraarterial injection of muscle-derived CD34+Sca-1+ stem cells restores dystrophin in mdx mice" *J. Cell Biol.* 152(2):335-348 (2001)). D3 has already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed October 26, 2004. D4 - D9 are being made of record in this Supplemental Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited documents.

Provided herewith is a copy of an Australian Examination Report, issued October 5, 2006, in connection with Australian Patent Application No. 2003236696 (Attorney Docket No. 17248-004AU1/ 4804AU). In the Australian Examination Report, Examiner cites two documents: D1 (US 6217847) and D2 (Rodriguez, *et al.*, "Expression of the firefly luciferase gene in vaccinia virus: A highly sensitive gene marker to follow virus dissemination in tissues of infected animals", *Proc. Natl. Acad. Sci. U.S.A.*, 85: 1667-1671 (1988)). D1 and D2 have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed October 26, 2004.

Provided herewith is a copy of an Indian Examination Report, issued October 23, 2006, in connection with Indian Patent Application No. 00004/MUMNP/2005 (Attorney Docket No. 17248-004IN1/ 4804IN). In the Indian Examination Report, Examiner cites two documents: 1) US 6217847 and 2) (Rodriguez, *et al.*, "Expression of the firefly luciferase gene in vaccinia virus: A highly sensitive gene marker to follow virus dissemination in tissues of infected animals", *Proc. Natl. Acad. Sci. U.S.A.*, 85: 1667-1671 (1988)). 1) and 2) have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed October 26, 2004.

Applicant : Szalay et al.  
Serial No. : 10/849,664  
Filed : May 19, 2004

Attorney's Docket No.: 17248-004002 / 4804B  
Supplemental Information Disclosure Statement

Provided herewith is a copy of a Chinese Office Action, with English translation, issued October 16, 2006, in connection with Chinese Patent Application No. 03812787.3 (Attorney Docket No. 17248-004CN1/ 4804CN). In the Chinese Office Action, Examiner cites one document: D1 (US 6217847). This document has already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449, filed October 26, 2004.

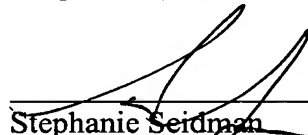
Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
11/529,662	09/27/06	17248-002003/4802C

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
\_\_\_\_\_  
Stephanie Seidman  
Reg. No. 33,779

Attorney's Docket No.: 17248-004002 / 4804B  
**Address all correspondence to:**  
Stephanie Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-4777  
Facsimile: (202) 626-7796  
email: seidman@fr.com

Substitute Form PTO-1449 (Modified)  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17248-004002/4804B	Application No. 10/849,664
	Applicant Aladar Szalay et al.		
	Filing Date May 19, 2004	Group Art Unit 1633	

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,093,700	07/25/00	Mastrangelo et al.	514	44	02/20/97
	AB	6,359,189	03/19/02	Fleischmann	602	41	01/14/00

**Foreign Patent Documents or Published Foreign Patent Applications**

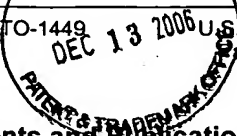
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AC	1020197	03/12/03	EP				X*
	AD	95/31105	11/23/95	PCT				
	AE	96/11279	04/18/96	PCT				
	AF	01/24637	04/12/01	PCT				

X\* = An English language equivalent is provided.

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AG	Cioffi et al., "A novel endothelial cell-based gene therapy platform for the in vivo delivery of apolipoprotein E," <i>Gene Therapy</i> , 6:1153-1159, (1999).
	AH	Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , 270:404-410, (1995).
	AI	Davis, "The Many Faces of Epidermal Growth Factor Repeats," <i>The New Biologist</i> , 2(5):410-419, (1990).
	AJ	Deng et al., "Engineering Ex Vivo-Expanded Marrow Stromal Cells to Secrete Calcitonin Gene-Related Peptide Using Adenoviral Vector," <i>Stem Cells</i> , 22:1279-1291, (2004).
	AK	Eck et al., "Gene-Based Therapy," <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , New York: McGraw-Hill, p77-101, (1996).
	AL	Gorecki, "Prospects and problems of gene therapy: an update," <i>Expert Opin. Emerging Drugs</i> , 6(2):187-198, (2001).
	AM	Kaufman et al., "A recombinant vaccinia virus expressing human carcinoembryonic antigen CEA," <i>Int. J. Cancer</i> , 48(6):900-907, (1991).
	AN	Kaufman et al., "Insertion of interleukin-2 (IL-2) and interleukin-12 (IL-12) genes into vaccinia virus results in effective anti-tumor responses without toxicity," <i>Vaccine</i> , 20:1862-1869, (2002).
	AO	Kaye et al., "A single amino acid substitution results in a retinoblastoma protein defective in phosphorylation and oncoprotein binding," <i>Proc. Natl. Acad. Sci. USA</i> , 87:6922-6926, (1990).
	AP	Kutinova et al., "Hepatitis B virus proteins expressed by recombinant vaccinia viruses: influence of preS2 sequence on expression surface and nucleocapsid proteins in human diploid cells," <i>Archives of Virology</i> , 134:1-15, (1994).
	AQ	Parrish et al., "Targeting widespread sites of damage in dystrophic muscle: engrafted macrophages as potential shuttles," <i>Gene Therapy</i> , 3:13-20, (1996).

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 17248-004002/4804B	Application No. 10/849,664
 <p><b>List of Patents and Publications for Applicant's Information Disclosure Statement</b></p> <p>(37 CFR §1.98(b))</p>				Applicant Aladar Szalay et al.	
				Filing Date May 19, 2004	Group Art Unit 1633
<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>					
Examiner Initial	Desig. ID	Document			
	AR	Perkus et al., "Recombinant Vaccinia Virus: Immunization Against Multiple Pathogens," Science, 229(4717):981-984, (1985).			
	AS	Pfleiderer et al., "A novel vaccinia virus expression system allowing construction of recombinants without the need for selection markers, plasmids and bacterial hosts," J. General Virology, 76:2957-2962, (1995).			
	AT	Rudinger, "Characteristics of the amino acids as components of a peptide hormone sequence", <i>Peptide Hormones</i> , Parsons, J.A.(Ed.), Baltimore: University Park Press, pp. 1-7, (1976).			
	AU	Sivanandham et al., "Therapeutic effect of a vaccinia colon oncolysate prepared with interleukin-2-gene encoded vaccinia virus studied in a syngeneic CC-36 murine colon hepatic metastasis model," Cancer Immunological Immunotherapy, 38:259-264, (1994).			
	AV	Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era," Trends in Biotech., 18:34-39, (2000).			
	AW	Torrente et al. "Intraarterial injection of muscle-derived CD34+Sca-1+ stem cells restores dystrophin in mdx mice," J. Cell Biol., 152(2):335-348, (2001).			
	AX	Van Damme et al. "Bone Marrow Stromal Cells as Targets for Gene Therapy," Curr. Gene Ther., 2:195-209, (2002).			
	AY	Verma et al., "Gene therapy- promises, problems and prospects," Nature, 389:239-242, (1997).			
	AZ	Williams, W. Sanders, "Southwestern Internal Medicine Conference: Prospects for Gene Therapy of Ischemic Heart Disease" The American Journal of the Medical Sciences, 306(2):129-136, (1993).			

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

12-15-06

Attorney's Docket No.: 17248-004002 / 4804B



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Aladar Szalay et al.  
Serial No. : 10/849,664  
Filed : May 19, 2004

Art Unit : 1633  
Examiner : Robert M. Kelly  
Cust. No. : 20985  
Conf. No. : 7765

Title : LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS  
AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR  
INFLAMED TISSUE

**Mail Stop: Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL**

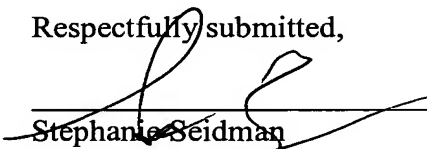
Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement (3 pages), Form PTO-1449 (2 pages), copy of European Examination Report, copy of Australian Examination Report, copy of Indian Examination Report, copy of Chinese Office Action with English translation, cited non U.S. patent documents, a check in the amount of \$180.00, and a return postcard for filing in connection with the above-identified application.

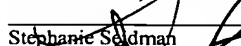


The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney's Docket No.: 17248-004002 / 4804B  
Address all correspondence to:  
Stephanie Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-4777  
Facsimile: (202) 626-7796  
email: seidman@fr.com

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EV 740126034 US  
Date of Deposit December 13, 2006  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.  
  
Stephanie Seidman